1. A method of immunizing a mammalian subject against at least one chronic immune-mediated disorder, and thereby reducing the risk of said subject developing said chronic immune-mediated disorder(s), which comprises:

(I) screening a plurality of immunization schedules, by

(a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism- associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule,

and

(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules is identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said

chronic immune mediated disorder(s),

where the first dose of at least one infectious disease-causing organism associated immunogen given to both groups is given sooner after birth according to the first screened immunization schedule than according to the second schedule (each such immunogen so administered to said first group being hereafter referred to as an "early" immunogen regardless of its time of administration in the second group),

Sub. a1

where one of said chronic immune-mediated disorders is diabetes,

where said mammalian subject is or said mammals are humans,

where at least one comparison (b) is made at least one year after first administration of an early immunogen to said mammals,

where at least one of said early immunogens is one other than BCG or pertussis immunogen, and

(II) immunizing said subject according to a third immunization schedule, according to which at least one of said early infectious disease-causing organism-associated immunogens is administered in accordance with said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

2. The method of claim 1 where the first dose of at least one early immunogen is given according to the first screened method starting at less than 42 days after birth.

3. The method of claim 2 where at least one of said

early immunogens is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, cocidiomycosis, schistosomiasis, and malaria immunogens.

4. The method of claim 3 where at least one of said early immunogens is a hepatitis B immunogen.

Sub. a7

5. The method of claim 2 where at least two immunogens are administered according to said third schedule, and such immunogens include (1) a first immunogen which was given prior to 42 days after birth to said first and second groups, and (2) a second and different immunogen which is an early immunogen.

6. The method of claim 5 where said first immunogen is a hepatitis B immunogen.

Sub. a3

7. The method of claim 6 where said second immunogen is given in the third schedule starting after 41 days after birth.

8. The method of claim 7 where the second immunogen is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavivirus, dengue,

toxoplasmosis, cocidiomycosis, schistosomiasis, and malaria immunogens.

Sub. a4

9. The method of claim 8 where the first dose of said second immunogen is given before 180 days after birth in the third schedule.

10. The method of claim 9 where said second immunogen is a killed immunogen.

Sub. a5

11. The method of claim 1 further comprising (III) screening said subject, during or after receipt of said third schedule, for the development of diabetes.

12. The method of claim 11 where subjects receiving said the third schedule are used to estimate the immunization related risk of developing diabetes.

13. The method of claim 12 where the incidence of diabetes is calculated in a group of subjects receiving said third schedule.

14. The method of claim 4 further comprising (III) screening said subject, during or after receipt of said third schedule, for the development of diabetes.

15. The method of claim 14 where said subjects receiving said third schedule are used to estimate the immunization-related risk of developing diabetes.

16. The method of claim 15 where the incidence of diabetes is calculated in a group of subjects receiving said third schedule.

17. The method of claim 10 further comprising (III) screening said subject, during or after receipt of said third schedule, for the development of diabetes.

18. The method of claim 17 where said subjects receiving said third schedule are used to estimate the immunization-related risk of developing diabetes.

19. The method of claim 18 where the incidence of diabetes is calculated in a group of subjects receiving said third schedule.

20. The method of claim 1 where the incidence of diabetes is compared.

21. The method of claim 4 where the incidence of diabetes is compared.

22. The method of claim 10 where the incidence of diabetes is compared.

23. The method of claim 1 where at least one comparison (b) is made when the subjects are at least age 5.

24. The method of claim 4 where at least one comparison (b) is made when the subjects are at least age 5.

25. The method of claim 10 where at least one comparison (b) is made when the subjects are at least age 5.

Sub. a6

26. The method of claim 4 where the first dose of at least one immunogen is given according to at least one of the first and second screened immunization schedules starting at less than 28 days after birth.

27. The method of claim 10 where the first dose of at least one immunogen is given according to at least one of the first and second screened immunization schedules starting at less than 28 days after birth.

28. The method of claim 4 where the first dose of at least one immunogen is given according to at least one of the first and second screened immunization schedules starting at less than 14 days after birth.

29. The method of claim 10 where the first dose of at least one immunogen is given according to at least one of the first and second screened immunization schedules starting at less than 14 days after birth.

30. A method of immunizing a mammalian subject against at least one chronic immune-mediated disorder and thereby reducing the risk of said subject developing said chronic immune-mediated disorder(s), which comprises

(I) (a) immunizing a first group of mammals with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a first screened immunization schedule, (b) immunizing at least a second group of mammals with one or more doses of one or more

infectious disease-causing organism-associated immunogens according to a second screened immunization schedule, the first and second groups being of the same species, and

(c) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups,

as a result of which one of said screened immunization schedules is identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),

where the first dose of at least one infectious disease-causing organism-associated immunogen given to both groups is given sooner after birth according to the first screened immunization schedule than according to the second schedule (each such immunogen so administered to said first group being hereafter referred to as an "early" immunogen regardless of its time of administration in the second group),

where one of said chronic immune-mediated disorders is diabetes,

where said mammalian subject is or said mammals are humans,

where said comparison (b) is made at least one year after first administration of said immunogen to said mammals,

where at least one of said early immunogens is one other than BCG or pertussis immunogen,

and

(II) immunizing said subject according to a third

immunization schedule, according to which at least one of said early, infectious disease-causing organism-associated immunogens is administered in accordance with said lower risk screened immunization schedule, resulting in a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

Sub. a6

31. The method of claim 30 where at least one early immunogen administered according to the first and third schedules is a hepatitis B immunogen.

32. The method of claim 30 where the hepatitis B immunogen is a killed immunogen administered prior to 42 days after birth, and at least one further immunogen is administered after 41 and before 180 days after birth in said first schedule, and said further immunogen is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, cocidiomycosis, schistosomiasis, and malaria immunogens.

33. The method of claim 1 where said mammals in the first and second schedule are randomly assigned to the first and second groups and said immunization schedules are part of a clinical trial for demonstrating efficacy against an infection or for demonstrating safety.

34. The method of claim 4 where said mammals in the first and second schedule are randomly assigned to the first and second groups and said immunization schedules are part

of a clinical trial for demonstrating efficacy against an infection or for demonstrating safety.

Sub. a6

35. The method of claim 10 where said mammals in the first and second schedule are randomly assigned to the first and second groups and said immunization schedules are part of a clinical trial for demonstrating efficacy against an infection or for demonstrating safety.

36. The method of claim 1 where the comparison (b) is made so as to compensate for at least one confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of diabetes or a second chronic immune mediated disorder, maternal infections while the mammal was in utero, infections during the first 12 months of life, size of the mammal at birth, gestational age of the mammal at birth, and exposure to vaccines.

37. The method of claim 4 where the comparison (b) is made so as to compensate for at least one confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of diabetes or a second chronic immune mediated disorder, maternal infections while the mammal was in utero, infections during the first 12 months of life, size of the mammal at birth, gestational age of the mammal at birth, and exposure to vaccines.

38. The method of claim 10 where the comparison (b) is made so as to compensate for at least one confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of diabetes or a second chronic immune mediated disorder, maternal infections while the mammals was in utero, infections during the first 12 months of life, size of the mammal at birth, gestational age of the mammal at birth, and exposure to vaccines.

39. The method of claim 1 where at least one chronic immune mediated disorder other than diabetes is also

compared.

40. The method of claim 4 where at least one chronic immune mediated disorder other than diabetes is also compared.

41. The method of claim 10 where at least one chronic immune mediated disorder other than diabetes is also compared.

42. The method of claim 1 where at least one comparison (b) is made when the humans are at least 5 years of age.

43. The method of claim 4 where at least one comparison (b) is made when the humans are at least 5 years of age.

44. The method of claim 10 where at least one comparison is made when the humans are at least 5 years of age.

Sub. a7

45. The method of claim 1 where the schedules also differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

46. The method of claim 4 where the schedules also differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

47. The method of claim 10 where the schedules also differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

48. The method of claim 1 where at least one infectious disease-causing organism-associated immunogen is administered to said subject so as to protect said subject against said infectious disease.

49. The method of claim 48 where at least two different immunogens are administered so as to protect the subject against at least two different infectious diseases.

50. The method of claim 48 where the immunogen protective against said infectious disease is an early immunogen.

51. The method of claim 1 where the schedules do not

Sub a8

differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

Sub. a8

52. The method of claim 4 where the schedules do not differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

53. The method of claim 10 where the schedules do not differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

51 ~~54~~. The method of claim 20 where there is a statistically significant difference in the incidence of diabetes between the first and second groups, or between a group of said subjects and a control group.

52 ~~55~~. The method of claim 1 where said lower risk of development of diabetes is evidenced by a lower incidence or frequency, or a slower onset, of diabetes.

53 ~~56~~. The method of claim 4 where said lower risk of development of diabetes is evidenced by a lower incidence or frequency, or a slower onset, of diabetes.

54 ~~57~~. The method of claim 10 where said lower risk of development of diabetes is evidenced by a lower incidence or frequency, or a slower onset, of diabetes.

55 ~~58~~. The method of claim 30 where said lower risk of development of diabetes is evidenced by a lower incidence or frequency, or a slower onset, of diabetes.

add a9

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